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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/813,463	01/11/2002	Kenneth G. Warren	098810/0278740	8427

7590 12/15/2004

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EXAMINER	
CHERNYSHEV, OLGA N	

ART UNIT	PAPER NUMBER
1646	

DATE MAILED: 12/15/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/813,463	WARREN ET AL.	
	Examiner	Art Unit	
	Olga N. Chernyshev	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 October 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *16-26* is/are pending in the application.

4a) Of the above claim(s) *16 and 17* is/are withdrawn from consideration.

5)☒ Claim(s) *21 and 23* is/are allowed.

6)☒ Claim(s) *18-20,22,24 and 25* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *15 April 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Response to Amendment

1. Claims 18-20 have been amended and claims 21-25 have been added as requested in the amendment filed on October 28, 2004. Claims 16-25 are pending in the instant application.

Claims 16-17 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 15.

Claims 18-25 are under examination in the instant office action.

2. The Text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

3. Any objection or rejection of record, which is not expressly repeated in this action has been overcome by Applicant's response and withdrawn.

4. Applicant's arguments filed on April 15, 2004 have been fully considered but they are not deemed to be persuasive for the reasons set forth below.

Priority

5. Applicant's petition to award filing date of March 20, 2001 to the instant application was granted on January 08, 2004.

Claim Rejections - 35 USC § 112

6. Claims 18-20, as amended and 22 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of predicting therapeutic efficacy of

treatment of multiple sclerosis (MS) with a peptide of 7 to 46 amino acids and having a sequence contained within amino acid residues 61-106 of SEQ ID NO: 1, provided that the peptide is capable of neutralizing or modulating the production of anti-myelin basic protein, by screening a multiple sclerosis patient for the presence of an HLA-DR2 haplotype, does not reasonably provide enablement for a method of predicting therapeutic efficacy of treatment of MS with a peptide of 7 to 46 amino acids from a fragment 61-106 of SEQ ID NO: 1, including substitutions, additions or deletions thereof, by screening an MS patient for the presence of an HLA-DR2 haplotype for those reasons of record as applied to claims 18-20 in section 8 of Paper mailed on May 29, 2003. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

Applicant traverses the rejection on the premises that "claims 18 to 20 and 22 do not require treatment of a multiple sclerosis patient. In fact, no treatment at all is being claimed. Thus, as treatment of multiple sclerosis patient is not being claimed, treatment of a multiple sclerosis patient need not be enabled" (bottom at first page of section I of the Response). This argument has been fully considered but is not deemed to be persuasive for the following reasons.

Claims 18-20 and new claim 22 are directed to a method of predicting therapeutic efficacy of treatment of multiple sclerosis (MS) by screening a MS patient for the presence of an HLA-DR2 haplotype. The nature of the invention is the demonstration that administration of a fragment of a MBP to MS patients leads to neutralization of anti-myelin basic protein and, consequently, to the treatment of MS. Therefore, although it is true that it is not the method of treatment of MS by administration of a fragment of MBP but a method of predicting efficacy of

such treatment is being claimed, in the instant case, there appears to be direct correlation between enablement of the method of treatment of MS and the enablement of the claimed method of predicting the efficacy of such treatment.

MPEP 2111.02, Effect of Preamble, states that "The determination of whether a preamble limits a claim is made on a case-by-case basis in light of the facts in each case; there is no litmus test defining when a preamble limits the scope of a claim. *Catalina Mktg. Int 'l v. Coolsavings.com, Inc.*, 289 F.3d 801, 808, 62 USPQ2d 1781, 1785 (Fed. Cir. 2002). "[A] claim preamble has the import that the claim as a whole suggests for it." *BellCommunications Research, Inc. v. Vitalink Communications Corp.*, 55 F.3d 615, 620, 34 USPQ2d 1816, 1820 (Fed. Cir. 1995). "If the claim preamble, when read in the context of the entire claim, recites limitations of the claim, or, if the claim preamble is necessary to give life, meaning, and vitality' to the claim, then the claim preamble should be construed as if in the balance of the claim." *Pitney Bowes, Inc. v. Hewlett-Packard Co.*, 182 F.3d 1298, 1305, 51 USPQ2d 1161, 1165-66 (Fed. Cir. 1999). See also > *Jansen v. Rexall Sundown, Inc.*, 342 F.3d 1329, 1333, 68 USPQ2d 1154, 1158 (Fed. Cir. 2003) (In considering the effect of the preamble in a claim directed to a method of treating or preventing pernicious anemia in humans by administering a certain vitamin preparation to "a human in need thereof," the court held that the claims' recitation of a patient or a human "in need" gives life and meaning to the preamble's statement of purpose.). *Kropa v. Robie*, 187 F.2d 150, 152, 88 USPQ 478, 481 (CCPA 1951) (A preamble reciting "An abrasive article" was deemed essential to point out the invention defined by claims to an article comprising abrasive grains and a hardened binder and the process of making it. The court stated "it is only by that phrase that it can be known that the subject matter defined by the claims is

comprised as an abrasive article. Every union of substances capable *inter alia* of use as abrasive grains and a binder is not an abrasive article.'" Therefore, the preamble served to further define the structure of the article produced). In the instant case, enablement of a method of predicting efficacy of treatment appears to be essential to the enablement of a method of treatment itself because it directly derives from and is based on that treatment. In other words, one skilled in the art would reasonably believe that it is impossible to predict therapeutic efficacy of treatment if the treatment itself is flawed or unpredictable.

The instant specification, as filed, provides guidance and scientific reasoning for a method of treatment of MS by administration of a fragment of MBP to a patient; therefore, the instant specification is considered to be enabled to predict efficacy of such treatment. However, the instant specification provides no guidance, working examples or any references to knowledge in the art on how to practice a method of treatment of MS by administering any peptide in existence ("a peptide of from 7 to 46 amino acids and having a sequence contained within amino acid residues 61-106 of SEQ ID NO: 1, including substitutions, additions or deletions thereof", claim 18). Because the instant specification fails to provide an adequate enabling disclosure for practicing such method of treatment, one skilled in the art would not know how to practice a method of predicting efficacy of such method of treatment of MS.

New grounds of rejection necessitated by amendment

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 24-25 are rejected under 35 U.S.C. 112, second paragraph, as failing to set forth the subject matter which applicant(s) regard as their invention. Evidence that claims 24-25 fail(s) to correspond in scope with that which applicant(s) regard as the invention can be found in Paper filed December 04, 2003. In that paper, applicant has stated that SEQ ID NO: 2 is an amino acid sequence, which is 7 amino acids long, and this statement indicates that the invention is different from what is defined in the claim(s) because claim 24 encompasses a method of using a peptide having a sequence different from the sequence recited in the Sequence Listing. Claim 25 depends from claim 24.

Conclusion

8. Claims 21 and 23 are allowed. Claims 18-20, 22 and 24-25 are rejected.

9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Olga N. Chernyshev whose telephone number is (571) 272-0870. The examiner can normally be reached on 8:00 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda G. Brumback can be reached on (571) 272-0961. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Certain papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax center located in Crystal Mall 1 (CM1). The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)). NOTE: If Applicant *does* submit a paper by fax, the original signed copy should be retained by Applicant or Applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers.

Official papers filed by fax should be directed to (703) 872-9306. If this number is out of service, please call the Group receptionist for an alternative number. Faxed draft or informal communications with the examiner should be directed to (571) 273-0870. Official papers should NOT be faxed to (571) 273-0870.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Olga N. Chernyshev, Ph.D.
Primary Examiner
Art Unit 1646

December 9, 2004